

# WoSRES

West of Scotland Research Ethics Service



Ms Alison Smith  
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**West of Scotland REC 1**  
Research Ethics  
Clinical Research and Development  
West Glasgow Ambulatory Care Hospital  
Dalnair Street  
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G3 8SW  
(Formerly Yorkhill Childrens Hospital)

Date 21 March 2017  
Direct line 0141 232 1807  
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Dear Ms Smith

**Study title:** **PRoBaND: Parkinson's Repository of Biosamples and Network Datasets: Prospective observational study of Parkinson's disease with repeat clinical assessment and biobanking of blood samples.**

**REC reference:** **11/AL/0163**

**Protocol number:** **52504/1**

**EudraCT number:** **None**

**Amendment number:** **Amendment 1.7, 19/01/2017 (REC Ref AM06)**

**Amendment date:** **15 February 2017**

**IRAS project ID:** **70980**

The above amendment was reviewed by the Sub-Committee in correspondence. This substantial amendment refers to a study extension for a further 4 year period from November 2016 to November 2020, for patients with Parkinson's disease of recent onset who have reached the end of the initial duration of participation (3 years), or the end of the interim extension period (i.e. 4.5 years of participation). It is also an extension for siblings of patients with Parkinson's disease. Patients and siblings will be eligible if they have completed the previous visits and have capacity to consent to these additional visits. The purpose of the changes are:

- a) To continue observations of the changes over time to document progression in Parkinson's and the emergence of any prodromal features of Parkinson's in siblings.
- b) To offer genetic counselling and the option of NHS gene tests, for participants whose research analysis of DNA indicates a likely mutation or variation linked to the development of Parkinson's.

The amendment also includes the introduction of two new documents information about research results for both the patients and relatives. A list of PI changes during the term of the study was also supplied.

## **Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

## Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>	
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance extension]		19 July 2016	✓
GP/consultant information sheets or letters [GP Letter Recruitment of Relative for Extension - Clean]	1.2	27 June 2016	✓
GP/consultant information sheets or letters [GP Letter Recruitment of Relative for Extension - Tracked Changes]	1.2	27 June 2016	✓
GP/consultant information sheets or letters [GP Letter Recruitment of Patient for Extension - Clean]	1.2	27 June 2016	✓
GP/consultant information sheets or letters [GP Letter Recruitment of Patient for Extension - Tracked Changes]	1.2	27 June 2016	✓
Notice of Substantial Amendment (non-CTIMP)	Amendment 1.7, 19/01/2017 (REC Ref AM06)	15 February 2017	✓
Other [Change of Principal Investigators]		18 January 2017	✓
Other [Information about research results - Patients ]	1.0	27 June 2016	✓
Other [Information about research results - Relatives]	1.0	27 June 2016	✓
Participant consent form [Patient Extension Consent Form - Tracked Changes ]	1.2	27 June 2016	✓
Participant consent form [Relatives Extension Consent Form - Clean ]	1.4	27 June 2016	✓
Participant consent form [Patients Extension Consent Form - Clean ]	1.2	27 June 2016	✓
Participant consent form [Relatives Extension Consent Form - Tracked Changes]	1.4	27 June 2106	✓
Participant information sheet (PIS) [Patient Extension PIS - Clean]	1.2	27 June 2016	✓
Participant information sheet (PIS) [Patient Extension PIS - Tracked Changes]	1.2	27 June 2016	✓
Participant information sheet (PIS) [Relatives Extension PIS - Tracked Changes]	1.3	27 June 2016	✓
Participant information sheet (PIS) [Relatives Extension PIS - Clean ]	1.3	27 June 2016	✓
Research protocol or project proposal [Tracked Changes]	1.5	24 June 2016	✓
Research protocol or project proposal [Clean ]	1.5	24 June 2016	✓

## Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

## Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

11/AL/0163:

Please quote this number on all correspondence

Yours sincerely

Abibat Akewumi

*On behalf of*  
**Dr Malcolm Booth**  
**Chair**

*Enclosures: List of names and professions of members who took part in the review*

*Copy to: Dr Joanne McGarry, NHS Greater Glasgow and Clyde*  
*Dr Donald Grosset, NHS Greater Glasgow and Clyde Health Board*

## West of Scotland REC 1

### Attendance at Sub-Committee of the REC meeting on 20 March 2017

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Peter Hutchison	GP (Vice Chair)	Yes	Chair of Meeting
Dr Iain Macpherson	Clinical Senior Lecturer in Medical Oncology (Clinical Trials Research)	Yes	
Mr James Timmons	IT Manager (Retired)	Yes	

#### Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Abibat Adewumi-Ogunjobi	Acting REC Manager